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institutional experience with comparable reporting provisions for drugs including biological products, and devices, information from industry representatives and trade organizations,

and data provided by the Eastern Research Group, a consulting firm hired by FDA to prepare an economic analysis of the potential economic impact on

sperm banks and other reproductive tissue facilities.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED INITIAL (ONE-TIME) REPORTING BURDEN<sup>1</sup>

21 CFR Section	Form FDA 3356	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
207.20(f)	Change to Form 3356	1	1	1	0.5	0.5
807.20(d)		66	1	66	0.5	33
1271.10(b)(1) and (b)(2), 1271.21(a), and 1271.25(a) and (b)	Initial registration and listing	300	1	300	0.75	225
Total						258.5

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	Form FDA 3356	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1271.10(b)(1) and 1271.21(b)	Annual Registration	1,003	1	1,003	0.5	501.5
1271.10(b)(2), 1271.21(c)(ii), and 1271.25(c)	Listing Update	484	1	484	0.5	242
1271.26	Registration Amendment	12	1	12	0.25	3
Total						746.5

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-1839 Filed 1-28-04; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003E-0147]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; FROVA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for FROVA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of two applications to the Director of Patents and Trademarks, Department of Commerce, for the

extension of two patents that claims that human drug product.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Claudia Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-453-6699.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the

amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product FROVA

(frovatriptan succinate). FROVA is indicated for the acute treatment of migraine attacks with or without aura in adults. Subsequent to this approval, the Patent and Trademark Office received two patent term restoration applications for FROVA (U.S. Patent Nos. 5,464,864 and 5,616,603) from Vernalis, Ltd., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated July 16, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of FROVA represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for FROVA is 2,201 days. Of this time, 1,186 days occurred during the testing phase of the regulatory review period, while 1,015 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* November 1, 1995. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 1, 1995.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* January 29, 1999. FDA has verified the applicant's claim that the new drug application (NDA) for FROVA (NDA 21-006) was initially submitted on January 29, 1999.

3. *The date the application was approved:* November 8, 2001. FDA has verified the applicant's claim that NDA 21-006 was approved on November 8, 2001.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,096 days of patent term extension for patent 5,464,864 and 586 days of patent term extension for patent 5,616,603.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments and ask for a redetermination by March 29, 2004.

Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 27, 2004. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2004.

Jane A. Axelrad,  
Associate Director for Policy, Center for Drug  
Evaluation and Research.

[FR Doc. 04-1840 Filed 1-28-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003E-0245]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; REMODULIN

AGENCY: Food and Drug Administration,  
HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for REMODULIN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Claudia Grillo, Office of Regulatory Policy (HFD-013), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-453-6699.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product REMODULIN (treprostinil sodium). REMODULIN is indicated as a continuous subcutaneous infusion for the treatment of arterial pulmonary hypertension in patients with NYHA class II-IV symptoms to diminish symptoms associated with exercise. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for REMODULIN (U.S. Patent No. 5,153,222) from United Therapeutics, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 16, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of REMODULIN represented the first permitted commercial marketing or use of the